K012019

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BIOMET
CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Orthopedics, Inc.
56 E. Bell Drive
Warsaw, Indiana 46582

Contact Person: Dalene T. Binkley
Telephone: (219) 267-6639
Fax: (219) 372-1683

Proprietary Name: Color Buffed (CB) DDH Femoral Stem

Common Name: Femoral Hip Stem

Classification Name: Hip joint metal/polymer semi-constrained cemented prosthesis.

Device Description: The Co-Cr-Mo Color Buffed DDH Femoral Stem is designed to replace a diseased or damaged femoral neck. The proximal area of the stem has been reduced slightly to allow a better fit in patients with more of a cylindrical canal.

Intended Use: The CB DDH Femoral Stem is intended for noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and revisions of hip replacement components.

Basis of Substantial Equivalence: The CB DDH Femoral Stem is nearly identical to the Color Buffed Cemented Femoral (K992903) that was cleared previously. The intended use, material, stem finish, diameter and over-all length is the same. The only minor changes to the femoral were the reductions in neck length and angle and proximal body.

Non-Clinical Testing: Mechanical testing was used to demostrate substantial equivalence.

Clinical Testing: Clinical data was not used for the support of this 510(K).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Dalene T. Binkley
Regulatory Affairs Specialist
Biomet, Inc.
P.O.Box 587
Warsaw, Indiana 46581

Re: K012019
Trade Name: Color Buffed (CB) DDH Femoral Stem
Regulatory Number: 888.3350
Regulatory Class: II
Product Code: JDI
Dated: June 26, 2001
Received: June 28, 2001

Dear Ms. Binkley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K012019

DEVICE NAME: Color Buffed (CB) DDH Femoral Stem

INDICATIONS FOR USE:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Donna Chelette for CMW

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012019